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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/827,484	GORE, MAKARAND	
	Examiner	Art Unit	
	Gollamudi S. Kishore	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-11,15,16 and 63-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 7-11, 15-16 and 63-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 5-19-09 is acknowledged.

Claims included in the prosecution are 1, 3-5, 7-11, 15-16 and 63-67.

In view of the terminal disclaimer, the double patenting rejection is withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-5, 7-8, 15 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (5,653,996).

Instant claims recite a jettable solution of plurality of vesicles and a pharmaceutical payload encapsulated within each of said vesicles and an edible outer medium with an intended use limitation that the material is jettable with an inkjet dispenser and properties of viscosity and surface tension.

Hsu discloses liposomal formulations containing phosphatidylcholines and phosphatidylglycerol in a buffer solution. The active agents include both water soluble and water insoluble active agents. The compositions further contain a surfactant, Tween which is considered as a solvent besides aqueous medium which is necessary for the formation of a liposome structure (abstract, col. 4, line 52 through col. 6, line 35, col. 9,

lines 28-35, examples and claims). The apparatus in Hsu produces both multilamellar and unilamellar liposomes. Although Hsu does not specifically teach the viscosity of the compositions, since instant claim 12 only recites that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Hsu posses the claimed viscosity. The intended use has no significance in composition claims. Applicant's arguments have been fully considered, but are not persuasive. As pointed out above, lipophilic (water insoluble) active agents sequester in both layers of the lipophilic phospholipids making up the bilayered liposomes in Hsu. Instant claim language 'comprising' does not exclude the lipophilic active agent sequestering also in the outermost layer of the bilayer. Since Hsu teaches water soluble active agents, they sequester within the aqueous core of the liposomes in Hsu reading on the second interpretation of the claim. The reference still reads on instant claims.

6. Claims 1, 3-5, 7-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlossmann (4,976,964).

Schlossmann discloses liposomal dispersions of Nifedipine and dihydropyridines. The phospholipids include phosphatidylcholine and phosphatidylserine. The formulations include glycerol (solvent) and buffers. The sizes of the liposomes are 50-100 nm (Col. 3, lines 20-51 and examples). Although Schlossmann does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Schlossmann posses the claimed viscosity. The intended use has no significance in composition claims.

7. Claims 1, 3, 5, 7-8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldrep (5,958,378).

Waldrep discloses liposomal formulations containing cyclosporin. The phospholipids include phosphatidylcholine (abstract, col. 5, lines 25-36, Examples and claims). Although Waldrep does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Waldrep posses the claimed viscosity. The intended use has no significance in composition claims.

Applicant provides no specific arguments for this rejection. As pointed out above, instant claims can be interpreted in two ways and the reference of Waldrep still reads on instant claims.

8. Claims 1, 3-5, 7-8, 10-11, 15 and 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach (5,160,669).

Wallach discloses paucilamellar vesicles containing the insecticide within the central cavity (abstract, col. 1, examples and claims). Wallach discloses further mineral oil which is a humectant (Table 2). The reference meets the requirements of instant claims.

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. Applicant argues the following:

"The Office Action concedes that Hsu, Schlossmann, Waldrep, and Wallach do not specifically teach the viscosity of the compositions of the jettable solution of claim 1, and, supposedly, claim 7. (Action, pp. 3, 6, and 7). As would be known of to one of skill in the art, and as explained in Applicant's

specification, at paragraph [0049] and elsewhere, in order to be jettable, a composition must have characteristics that will allow it to be delivered given the pressures, temperatures and other parameters of an inkjet material dispenser while protecting the pharmaceutical payload. For example, for a solution to be "jettable" it must have a certain viscosity and surface tension. (See e.g., Applicant's specification, paras. [0049] and [0059]). Whether or not the claimed solution is "jettable" is of immense significance. Specifically, as described in Applicant's specification, The precise metering capability of the inkjet material dispenser (150) along with the ability to selectively emit the metered quantity of aqueous vesicle pharmaceutical (160) onto precise, digitally addressed locations makes the present system and method well suited for a number of pharmaceutical delivery applications. According to one exemplary embodiment, the precision and addressable dispensing provided by the present inkjet material dispenser (150) allows for one or more compositions to be dispensed on a single edible structure (170). According to this exemplary embodiment, a combination therapy may be produced in a customized dosage for a patient. (Applicant's specification, para. [0054]). Thus, with the claimed jettable composition, a prescribing physician can order "a customized dosage for a patient" that is then produced by a pharmacist with an inkjet material dispenser, similar to an inkjet printer. (Id.). Without the jettable solution of Applicant's invention, producing a customized dosage for each patient would be unreasonably expensive. (Applicant's specification, para. [0059]). Consequently, the patient may have to ingest a much larger, standardized dosage of a pharmaceutical than the patient actually needs. The Office Action states that "it is the examiner's position, in the absence of showing otherwise, that the compositions of Hsu [, Schlossmann, Waldrep, and Wallach] posses the claimed viscosity." (Action, pp. 3, 6, and 7). The Office Action further states that "it is still the examiner's position that Hsu's preparations are jettable and applicant has not shown that [to] be otherwise." (Action, p. 5)(emphasis added). However, Applicant wishes to point out that it is incumbent upon the Examiner to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, because the Examiner failed to identify, in Hsu, Schlossmann, Waldrep, or Wallach, a jettable solution wherein the jettable solution is jettable with an inkjet material dispenser, a prima facie case of

anticipation has not been established. Further, in contrast to the claimed subject matter, none of the cited prior art references teach or suggest the claimed jettable solution with a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter. This subject matter and its advantages are entirely outside the scope and content of the cited prior art. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on any of Hsu, Schlossmann, Waldrep, or Wallach of claims 1 and 7 and their dependent claims should be reconsidered and withdrawn. Finally, with regard to claim 7, the Office Action fails to specifically address claim 7 or to indicate how or where the cited prior art teaches the specific subject matter of claim 7."

These arguments are not persuasive for the following reasons. First of all, instant claims recite the properties such as surface tension and viscosity of the solutions and the Patent Office is not equipped to determine whether the solutions of the prior art possess these properties or not. Secondly, Hsu uses either water or buffer solutions in the preparations of liposomes. Waldrep uses aqueous solution of liposomes. Schlossmann uses phosphate buffer to make liposomal solutions . Wallach uses aqueous solutions of liposomes containing either water or 1.5 % surfactant. Instant claims recite a viscosity of less than 5 centipoises implying very low viscosity the surface tension between 25 and 60 dynes per centimeter; it is well known that water viscosity is less than 5 centipoise and surface tension of 72 dynes per centimeter. The examiner cites as interest the reference of Breton (5,626,654) which teaches liposomal solutions containing aqueous solutions containing even 40 % glycerol and pH adjusting agents such as acetic acid and phosphate salts and surface modifiers have claimed

viscosity and surface tension (see col. 20 line 22 through col. 22, line 37). Therefore, it is the position of the examiner that the references have the same claimed viscosity and surface tension properties in the absence of showing otherwise.

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3, 8, 10-11, 15 and 67 are rejected under 35 U.S.C. 102(a) as being anticipated by Hainfeld (6,645,464).

Hainfeld teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery taught by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims). The reference meets the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are similar to those raised for the rejections of the claims over Hsu, Wallach and Waldrep. Since Hainsfeld teaches the use of phosphate buffered saline (see claim19), the vesicular solutions taught by Hainsfeld would have the same claimed viscosity and surface tension properties; applicant has not shown that to be otherwise.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu or Schlossmann or Waldrep or Hainfeld cited above.

The teachings of Hsu, Waldrep and Schlossmann have been discussed above. It is unclear from these references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming that the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts of the phospholipids to form required population of liposomes and suspend them in a suitable amount of vehicle. Since the amounts of the active agent depend upon the condition to be treated, this parameter is deemed to be a variable parameter.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues the following:

"According to the Action, "[i]t is unclear from these [prior art] references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts." (Action, p. 7). This is an insufficient analysis on which to reject claim 16 under prevailing case law. The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in KSR International Co. v. Teleflex Inc., 550 U.S._, 82 USPQ2d 1385 (2007): "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."

Quoting Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, "[a]ll claim limitations must be considered" because "all words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385. With regard to claim 16, the Office Action fails to determine the exact scope and content of the cited prior art and the differences between the cited prior art and the claimed subject matter. Rather, the Action finds it "unclear" whether the elements of the claimed composition is taught by the prior art. (Aciton, p. 7). Nevertheless, the Action, without supporting evidence, makes the conclusory statement that the claimed composition would be obvious."

These arguments are not persuasive. Instant claims are composition claims and the examiner has already addressed the issue of jettability of the prior art compositions. The motivation to change the amounts of the ingredients need not be the same as applicants in composition claims. Therefore, the rejection is maintained.

12. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu, Schlossmann, Waldrep, Wallach (5,160,669) or Hainfeld cited above in view of Handjani (4,608,211).

The teachings of Hsu, Schlossmann, Waldrep, Wallach (5,160,669) or Hainfeld have been discussed above. What is lacking in these references is the inclusion of antifoaming agents. Such an inclusion however, with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since the reference of Handjani shows the routine practice of adding an antifoaming agent in liposomal compositions (col. 4, lines 1-15).

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that neither Wallach nor Handjani teach or suggest a composition with an antifoaming agent that is effective to prevent foaming of the solution and that Handjani actually teaches that the anti-foaming agent is introduced into the aqueous phase to be encapsulated. This argument is not persuasive. First of all, it is common

knowledge that an anti-foaming agent is used to prevent foaming and therefore, if there is a surfactant in the composition or the composition has foaming properties one should be using an anti-foaming agent. Proteins taught by Handjani are surfactants and therefore, he teaches the use of anti-foaming agents. Secondly, a close examination of the examples indicates that the lipids are hydrated with an aqueous solution containing glucose (active agent) and the active agent is not separated. Since such a procedure results in the presence of glucose in the aqueous interior as well as outer aqueous medium, one of ordinary skill in the art would expect similar distribution when proteins are used as drugs in the aqueous medium and therefore, one of ordinary skill in the art would inter the presence of anti-foaming agent both in the aqueous interior as well as the in the outer aqueous medium in which the liposomes are suspended.

13. Claims 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach (5,160,669) cited above in view of Schlossmann (4,976,964).

The teachings of Wallach have been discussed above. What is lacking in Wallach is the inclusion of rheology adjusting agent and pH adjusting agents. Such an inclusion however, with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since the reference of Schlossmann shows the routine practice of adding buffers and glycerol in liposomal compositions (col. 3, line 27 through col. 4, line 66).

Applicant argues that the rejection refers to Handjani and that there is no teaching of buffers and glycerol in Handjani. The examiner points out that the rejection

is made over the combination of Wallach and Schlossmann and the examiner inadvertently referred to Handjani instead of Schlossmann.

14. Claims 1-3, 5, 7, 10-11, 15-16 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hainfeld (6,645,464).

Hainfeld as pointed out above teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery suggested by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims). Although Hainfeld discusses the liposomal formulations, he does not teach how to prepare the liposomal compositions to be delivered through ink jet delivery. However, since liposomal preparations, both unilamellar and multilamellar, are well known in the art, it would have been obvious to prepare them by art known techniques to be used in ink jet delivery systems. Since phospholipids are routinely used in the preparation of liposomes, selecting the specific phospholipids such as phosphatidylcholine and phosphatidylethanolamine is deemed to be within the skill of the art.

15. Claims 1, 3-5, 7-11, 15-16 and 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (5,911,816) in view of Hainfeld (6,645,464) or Schlossmann cited above by themselves or in combination or vice versa (Schlossmann or Hainfeld individually or in combination in view of Gore).

Gore discloses liposomal compositions containing the claimed ingredients and additives as jettable solutions to be used with ink jets (abstract, columns 2-5, examples

and claims). Gore does not however, teach the incorporation of biologically active agent to be used in the inkjet delivery device.

Hainfeld as pointed out above teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery suggested by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims).

The teachings of Schlossmann have been discussed above.

To include a pharmaceutical payload in the jettable compositions of Gore would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of Hainfeld and Schlossmann teach that the vesicular compositions containing drugs can be prepared and Hainfeld in particular teaches that liposomes can be loaded with pharmaceutical agents to be delivered by inkjet devices. Alternately to prepare specific liposomal compositions containing phospholipids with the additional buffers, biocides and others in the generic teachings of ‘vesicles’ or 'liposomes’ taught by Hainfeld would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Gore teaches that such solutions are jettable using ink jet devices. The criticality of specific active agents is not readily apparent since the nature of the active agent depends upon the disease to be treated.

Applicant’s arguments have been fully considered, but are not persuasive. Applicant argues that instant claims 1 and 7 recite the viscosity of less than 5 centipoise

and a surface tension between approximately 25 and 60 dynes per centimeter and in contrast, Gore, Hainsfeld and Schlossmann do not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inject material dispenser. This argument is not persuasive since on col. 5, lines 18-25 Gore clearly teaches the same claimed parameters. While conceding that Hainsfeld teaches 'ink jet delivery', applicant argues that Hainsfeld does not teach or suggest that such 'in jet delivery' comrprises a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet dispensor. These arguments are not persuasive since jettability of a solution depends on the viscosity and surface tension, one of ordinary skill in the art would be motivated to manipulate these parameters of the solution to obtain the best possible results. It is a routine experimentation by the practitioner of the art. Furthermore, one of ordinary skill in the art would be motivated to use the claimed values since the reference of Gore shows that the liposomal solutions having these properties are routinely used for ink jet printing. Applicant further argues, "in fact, this the only portion of Hainsfeld that discusses ink jet delivery, and does so in passiing without any details as the particulars of the ink jet delivery process or the composition of the solution passingto be jetted through an ink jet nozzle. This argument is not persuasive since ink jet delivery of liposomal solutions is well known in the art as evident from Gore.

Applicant argues that Schlossmann teaches away since dihydropyridines taught by Schollsmann are dispersed in the membrane of the liposomes and that such dihydropyridines are not water-soluble, thus, precluding them from being enclosed in the aqueous inner volume of the vesicles. The rationale behind this argument is not readily apparent to the examiner since instant claims only recite, "a pharmaceutical payload encapsulated within each of said vesicles" and this limitation does not exclude lipophilic material encapsulated within the liposomal membrane. Furthermore, instant claim 9 recites several lipophilic active agents including 'dihydropyridines taught by Schlossmann which applicant argues as water insoluble.

16. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore whose telephone number is (571)

272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK